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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,156	11/13/2001	Atso Raasmaja	0933-0176P	6431

2292 7590 03/09/2004

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary**Application No.**

09/987,156

Applicant(s)

RAASMAJA ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/30/2001</u> . | 6) <input type="checkbox"/> Other: ____ |

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

The post office address of inventor Lampela has been altered without initials or a date of the change.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Steer et al (A, newly cited).

The claimed invention is drawn to a composition for transfecting a cell, comprising one of more nucleic acid molecules, polycations or cationic polymers and cationic liposomes or

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lipids; more narrowly claimed in claim 2 as comprising two or more polycations or cationic polymers and cationic liposomes or lipids; the cationic polymers more narrowly claimed in claim 3 as polyethyleneimine (PEI), further limited to 700, 200 or 25,000 daltons in claim 5, or “especially low molecular weight” in claim 6; the cationic liposome more narrowly claimed in claim 4 as DOSPER, further limited in claim 9 to a liposome:DNA charge ratio of 0.5 to 50; the nucleic acid limited to comprising a gene-encoding plasmid in claims 8 and 12. Claim 7 is worded such that it cannot be understood (see the rejection under 35 USC § 112, second paragraph, below), and so its limitations are treated as those of any of the claims from which it depends. Claims 10 and 11 recite a nearly exhaustive listing of nucleic acids including DNA, RNA, nonviral expression plasmids and viral vectors, among others. (However, the nucleic acids may be interpreted as claimed in combination instead of in the alternative. See the rejection under 35 USC § 112, second paragraph, below.) Claim 13 is drawn to a use of the composition of claim 1 “for synergistic potentiation of transfection efficiency.” However, this limitation is unclear, particularly in the limitation to “synergistic”, as it is not clear between what elements or steps synergy is specified. (See the rejection under 35 USC § 112, second paragraph, below). As such, the claim is taken to read on, at least, simply a method of transfection employing the invention of claim 1.

Steer et al. teaches, e.g., at column 13, line 41 through column 14, line 24, the construction of a composition of CMV vector and a lipid, DOSPER being taught at column 13, line 67, and PEI (line 62). At the paragraph bridging the columns, a ratio of 4:1 imine:phosphate is taught, leading to a charge ratio of “liposome/DNA” as found in claim 9, of 0.25; however, the following paragraph teaches a reduction of this ratio with anionic phospholipids at a 2:1 ratio

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over the other lipids, such that 0.5 ratio overall would be achieved. At the first full paragraph of column 12, PEI molecular weights of greater than 500 and of about 25,000 daltons are taught. Furthermore, 500 daltons would have been considered a low molecular weight PEI. At column 14, lines 15-24, the disclosed transfection method using a plasmid is taught. The Abstract generally teaches the use of the disclosed compositions for transfecting animal cells, which would anticipate claim 13 for reasons set forth above.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 provides for the use of the composition of claim 1, as recited, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and therefore dependent claims 2-13, recite the elements of the composition as “one or more nucleic acid molecules, polycations or cationic polymers, and cationic liposomes or lipids.” However, it is not clear which genera of molecules are required to be included, or are merely set forth in the alternative. For example, are nucleic acids set forth in the alternative to “polycations or cationic polymers”? Or are all three in the alternative to one another, and in combination with “cationic liposomes or lipids”? Careful reconsideration of the wording of the claim is suggested, to clarify the invention.

Claim 6, and therefore dependent claim 7, recites the term “especially low molecular weight”. However, this term has no definition in the art or the specification.

ALTERNATIVELY, it would appear that the claim could be understood such that “especially” modifies the second occurrence of “polyethyleneimines” as the noun, in which instance “especially” renders the scope of the claim unclear, as it is not clear if that which follows the phrase is limiting of the scope of the claim, i.e., are the “polyethyleneimines” recited as the first occurrence of the term limited to “low molecular weight polyethyleneimines being ineffective alone and effective in combinations”?

With further respect to claim 6 (and therefore 7), the phrase “being ineffective alone and effective in combinations” does not make clear to what end or outcome the polyethyleneimines are “ineffective” or “effective”, and what degree of functionality in that context represents

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“effective”. Furthermore, the term “in combinations” does not specify with what is the polyethyleneimine combined. As such, the metes and bounds of the claim are unclear.

Claim 7 recites “the amount of transfection reagents is very low being inefficient when used alone.” However, this phrase is grammatically disjointed, appearing to be missing a word or phrase, such that its meaning is not at all apparent. The phrase “being inefficient when used alone” appears to be merely tacked on, rendering the claim unclear.

Claims 10 and 11 recite a number of types or genera of nucleic acids. However, such are recited in combination, rather than in the alternative, which does not reflect the invention as disclosed in the specification. It would appear that alternative recitation was intended, i.e., “or”.

Claims 10 and 11 also recite the phrase “for example” which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 10 and 11 also recite the term “plain nucleic acids” (misspelled as “plaim” in claim 11). However, it is not clear what this term means, i.e., how “plain” limits “nucleic acids.”

Claim 12 recites the term “specific genes”. However, it is not clear what would distinguish a “specific” gene from any other gene. As such the metes and bounds of the instant claim are unclear.

Claim 13 recites the phrase “for synergistic potentiation of transfection efficiency.” However, this limitation is unclear, particularly in the limitation to “synergistic”, as it is not clear between what elements or steps synergy is specified. Furthermore, the term “potentiation” does not have a clear meaning within the context of the recombinant DNA art. As such, the meaning of the claim is not clear.

Certain papers related to this application, OTHER THAN OFFICIAL RESPONSES, may be submitted directly to the Examiner by facsimile transmission at (571) 273-0770. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). (703) 872-9306 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter fax number unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
March 5, 2004


JAMES KETTER
PRIMARY EXAMINER